

Claims 1-5,25-27, 36-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the RCE filed 9/17/08, applicant amends claim 1 and adds new claims 36-39 to include the limitation of "washing the column with 0-10% alcohol"; the specification does not disclose this step. Example 4 pointed by applicant only discloses washing with water. Also, there is no disclosure of the range 15-40% or 15-20%. Example 4 discloses 10%, 15%, 20% and 40%; however, the ranges claimed contain values not disclosed in the set. For example, there is no disclosure of 25,30, 18,19 % etc.. There is no disclosure of washing with ethanol as recited in claim 26.

Claim 39 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 39 is vague and indefinite because claim 1 recites "styrene-divinylbenzene absorbent resin and claim 39 recites the resin is "Diaion HP-20". It is not clear what the resin is or are the two resins the same thing. Furthermore, the use of Trademark name in the claim is indefinite.

Claims 1-5,25-27 and 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pihlava et al (WO 02/062812) in view of Ottenstein et al (5637135)

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Pihlava et al disclose a process for preparing an SDG-rich food comprising the step of extracting a plant material containing SDG with a basic alcohol. The plant material is defatted flaxseed. The basic alcohol is sodium hydroxide-methanol. The SDG can be enriched by chromatography. For instance, a mixture having the SDG mixed with c18 material is packed in a flash chromatography system. The column is finally equilibrated with water-methanol or water-ethanol used as the eluant. SDG is eluted from the sample cartridge with a water-methanol or water-ethanol mixture. The column is washed with methanol-water or ethanol-water. The sample-c18 mixture can also be packed into an open c18-chromatography column and SDG can be correspondingly eluted therefrom with methanol or ethanol. The flaxseed is ground to a particular powder. The example on page 6 lines 29-30 discloses that SDG is eluted with 650ml of 40% methanol. (page 2, lines 21-28, page 3 lines 25-31, page 4 lines 20-30 and the example)

Pihlava et al do not disclose the concentration of alcohol as in claims 4,25, the temperature as in claims 27, washing with the alcohol concentration as in claims 1,37, eluting with alcohol concentration as in claims 37-38 and the resin as claimed.

Ottenstein et al discloses chromatographic separation columns. They teach all materials such as silica gel, porous silica, activated carbon, styrene divinylbenzene resins etc... are all well known materials for use in packed columns. (see col. 1 lines 35-49)

Pihlava et al teach enriching for SDG on the column; thus, Pihlava et al teach applying the extracted solution to a resin column. Pihlava et al teach washing with

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water and water-alcohol solution; it would have been obvious to one skilled in the art to determine the appropriate alcohol concentration to obtain the most optimum product. The concentration used is a result-effective variable which can readily be determined through routine experimentation. It would have been within the skill of one in the art to determine the appropriate concentration of alcohol to obtain the most optimum extraction. The amount is a result-effective variable which can readily be determined by one skilled in the art through routine experimentation. It would also have been obvious to one skilled in the art to determine the appropriate temperature through routine experimentation to obtain the most optimum extraction. Applicant has not shown criticality or unexpected result with respect to the temperature. Pihlava et al teach the use of different column material; however, as shown by Ottenstein et al, the material used by Pihlava et al and the claimed method are all well known stationary phase material in chromatography. Thus, it would have been obvious to one skilled in the art to substitute one well known column material for another well known column material. The use of a specific brand name material would have been an obvious matter of preference.

In the RCE filed 9/17/08, applicant argues the claims are supported by the specification. Applicant points out that alcohol of 0,10,15,20 and 40% has been used in the experiment to purify SDG and that SDG is barely washed out by alcohol of 10% or less and SDG is enriched with alcohol of 15-40%. This argument is not persuasive because it does not point to the teaching of washing with alcohol. There is no question concerning the support for purifying with alcohol or enriching with alcohol or eluting with

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alcohol. The issue is raised with respect to washing with alcohol and applicant has not pointed to the specific teaching of the limitation. Page 18 lines 3, 10 discloses " after washing with water"; there is no disclosure of washing with alcohol. Applicant states the meaning of " washing" or " eluting" should not be interpreted literally. The terms are interpreted according to the disclosure. The specification clearly discloses two separate steps of washing and eluting; there is no disclosure of " washing being the same as eluting" and that the solution used for eluting is also used for washing. The teaching pointed out by applicant is all directed at " eluting". With respect to the range of 15-40, applicant argues the law does not require the disclosure of individual concentration within the range of 15-40%. The issue here is that applicant does not disclose the range in the specification and the values disclose in the specification does not support the range as claimed. The alcohol concentration in original claim 4 is for the extracting of the SDG, not the alcohol used for eluting the column.

With respect to the 103 rejection, applicant argues Pihlava discloses reverse-phase partition chromatograph while the current claims utilize adsorption chromatography and that the Pihlava is only appropriate as a small scale purification technique, not a large scale technique. This argument is not persuasive. There is no limitation in the claims that differentiate partition chromatography from adsorption chromatography or small scale preparation versus large scale preparation. The issue of different resin material is addressed in the rejection above. The steps as disclosed in Pihlava are consistent with the steps disclosed in the article " Thin-Layer Chromatography". The main point is that the claimed steps do not differentiate from

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Pihlave. The claims recite applying the extracted solution on a column, washing and eluting the material with alcohol; these are the steps taught by Pihlava. Applicant also makes argument with respect to the amount of flaxseed that can be processed. This argument does not commensurate with the claims as there is no limitation in the claims with respect to the amount of flaxseed to be processed.

. Applicant also argues that there must be some sort of teaching or motivation to vary the amount of a variable. This argument is not persuasive. The examiner maintains her position that the concentration of alcohol used in a result-effective variable which can be determined through routine experimentation to obtain the most optimum extraction. A 103 rejection must take into consideration the skill of one in the art. In doing the extraction, it is inherent that a certain concentration of alcohol is used. If after a run, it is determined that the concentration of alcohol used does not give the most desirable extraction, it would have been readily apparent to one skilled in the art to experiment with various concentrations to obtain the most optimum extraction. The experiment is not undue and would have been within the skill of one in the art. Applicant has not shown any unexpected result or criticality with respect to the amount claimed. In fact the amount claimed is a conventional amount used for extracting SDG as shown in Jp9-208461 in the IDS submitted with the amendment.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lien T. Tran whose telephone number is 571-272-1408. The examiner can normally be reached on Monday-Thursday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on 571-272-1398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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October 14, 2008

/Lien T Tran/

Primary Examiner, Art Unit 1794